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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,186	07/20/2001	Leonard A. Smith	A33626A 067252.0107	8442

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/910,186	Smith et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 20, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *39-86* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *39-86* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-38 have been canceled.

Claims 39-86 are new pending claims.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 39-51, 53-56, 82 and 86 (species directed to carboxy-terminal), drawn to a plurality of inventions directed to isolated nucleic acid molecule comprising a sequence for the (carboxy) C-terminal of the heavy chain of botulinum neurotoxin B, or C1 or D or E or F or G, a recombinant host cell comprising the nucleic acid sequence and a method of using the nucleic acid to express the encoded polypeptide through culturing the recombinant host cell, classified in class 514, subclass 44 .

II. Claim 52, drawn to a plurality of inventions directed to immunogenic compositions comprising the carboxy-terminal of the heavy chain of botulinum neurotoxin serotype-B, or C1 or D or E or F or G, classified in class 424 , subclass 239.1.

III. Claims 57-71, 73-74, 82 and 86 (species directed to the amino terminal portion) drawn to a plurality of inventions directed to isolated nucleic acid comprising a

sequence that encodes the (amino) N-terminal portion of botulinum neurotoxin serotype B, or C1 or D or E or F or G, a recombinant host cell comprising the nucleic acid sequence and a method of using the nucleic acid to express the encoded polypeptide through culturing the recombinant host cell classified in class 536, subclass 23.7 .

IV. Claim 72, drawn to a plurality of inventions directed to immunogenic compositions comprising the N-terminal of the heavy chain of botulinum neurotoxin serotype-B, or C1 or D or E or F or G, classified in class 424, subclass 239.1.

V. Claims 75-79, drawn to a plurality of inventions directed to immunogenic compositions that comprises any portion of botulinum serotype-B, or C1 or D or E or F or G, heavy chain, classified in class 530, subclass 300 .

VI. Claims 80-81 and 83-84, drawn to a plurality of inventions directed to a nucleic acid that comprises a sequence for at least one epitope of the heavy chain of botulinum serotype B, or C1 or D or E or F or G, classified in class 536, subclass 23.4.

VII. Claims 82, 85-86, drawn to a plurality of inventions directed to n recombinant cell that comprises a nucleic acid sequence that encodes both the N-terminal and C-terminal of botulinum neurotoxin serotype-B, or C1 or D or E or F or G, classified in class 435, subclass 69.1.

2. Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention Group I and III have separate utility such as stimulating distinct immune responses to either the N-terminal or C-terminal of botulinum neurotoxin. See MPEP § 806.05(d).

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, evidence different modes of operation, different functions, and different effects, wherein a nucleic acid structurally differs from that of an immunogenic composition that comprises amino acids, each molecule evidencing different binding specificities and biological activity .

4. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, evidence different modes of operation, different functions, and different effects, wherein a nucleic acid structurally differs from that of an immunogenic composition that comprises amino acids, each molecule evidencing different binding specificities and biological activity .

5. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, evidence different modes of operation, different functions, and different effects, wherein a nucleic acid structurally differs from that of an immunogenic composition that comprises amino acids, each molecule evidencing different binding specificities and biological activity.

6. Inventions VII and either Group I or III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention of Group VII is able to express and stimulate an immune response to both the N-terminal and C-terminal portions, while either Group I or III will only express and stimulate an immune response to one terminal, wherein the immune response has separate utility such as in methods of purifying specific portions of the neurotoxin,

or in the formulation of a sandwich immunoassay that would require antibodies directed to different terminal of the neurotoxin. See MPEP § 806.05(d).

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and because the searches required for the separate groups of inventions are non-coextensive, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. All of the claims are directed to a plurality of disclosed patentably distinct products comprising materially different nucleic acids or polypeptides. Should the invention of Groups I, or II or III, or IV or V or VI or VII be elected, Applicant would be required under 35 U.S.C. 121 to elect a single disclosed product, even though this requirement is traversed.

Each separate nucleic acid encodes a polypeptide represented by a separate SEQ ID No and is associated with a neurotoxin that has differing structural and biological activity, therefore

each particular polypeptide product claimed would require a separate area of search and consideration tailored to the particular product under consideration.

The separate polypeptide is encoded by a separate SEQ ID NO and associated with a neurotoxin that has differing structural and biological activity, therefore each particular polypeptide product claimed would require a separate area of search and consideration tailored to the particular product under consideration.

10. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election of a single SEQ ID NO pair for a specific neurotoxin, relative to the desired Group from the SEQ ID Nos claimed:

Claimed SEQ ID Nos heavy chain : B:7, 8; C: 9, 10; D: 11,12; E: 13, 14; F:15,16; G: 17,18.

Claimed SEQ ID Nos N-terminal:B:21,22; C:23, 24; D:25, 26; E:27,28; F:29,30; G:31,32.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
July 15, 2002

L. F. S.
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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